



STUDY OF VARIABLES IMPACT ON THE OUTCOME OF ESWL PROCEDURE IN TREATMENT OF UROLITHIASIS

Urology

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ABSTRACT

Background: Open surgery was considered as the mainstay of treatment of renal calculi up to the eighties. With the rapid development of minimally invasive surgery (minimal access surgery) since then, endourology replaced open surgery as the treatment of choice for most urinary calculi. Almost simultaneously came the advance in the form of a completely non-invasive approach in the form of ESWL. This revolutionized treatment of urinary calculous disease either as a monotherapy or in combination with endourological procedures such as percutaneous Nephrolithotripsy and ureterorenoscopy, replaced open surgery almost completely.

Materials & Methods: A prospective study was carried out on 90 patients presented to the surgical OPD of tertiary care teaching hospital in Mumbai between October 2013 to April 2015 with Urolithiasis. After taking complete history a thorough clinical examination done & required investigations performed. Patients were then underwent ESWL. All the post procedure findings were recorded under specific parameters.

Results & Conclusions: Based on results of our study and interpreting it in the context of available literature on the subject we reached the following conclusions; ESWL is an excellent, safe, non-invasive modality with minimal morbidity, hospital stay and complications for the treatment of a certain subset of patients with urinary calculi in the kidney and to the level of the mid ureter up to 2.5cm in size. There are several variables affecting the outcome of ESWL and this is the most important thing to be kept in mind in trying to achieve a complete stone free state in a patient.

KEYWORDS

ESWL, PCNL, URS, UROLITHIASIS.

INTRODUCTION

Open surgery was considered as the mainstay of treatment of renal calculi up to the eighties. With the rapid development of minimally invasive surgery (minimal access surgery) since then, endourology replaced open surgery as the treatment of choice for most urinary calculi. Almost simultaneously came the advance in the form of a completely non-invasive approach in the form of ESWL. This revolutionized treatment of urinary calculous disease either as a monotherapy or in combination with endourological procedures such as percutaneous Nephrolithotripsy and ureterorenoscopy, replaced open surgery almost completely. This happened to the extent that for most renal and ureteric calculi open surgery is contemplated only if there is a specific contraindication to ESWL or endourology either alone or in combination. In this context ESWL appears the most attractive option since it is totally non-invasive in nature. In addition there are the advantages of a short stay in hospital, (the procedure being possible even on an outpatient basis with the patient returning home the same day), no requirement of anaesthesia in the majority of patients and no wound related complications.

AIMS AND OBJECTIVES

- To identify the variables which can impact the outcome of ESWL in patients undergoing this procedure for treatment of their urinary calculi up to 2.5cm in size.
- Study each of these variables individually, as well as in combination, so as to analyze and evaluate their impact on the outcome of the procedure and reach appropriate conclusions with a view towards improving quality of patient care.

MATERIALS AND METHODS.

- Study site:** Patients attending surgical outpatient department and admitted in surgical wards for ESWL at a tertiary level teaching hospital.
- Study population:** Patients predominantly from the surrounding urban areas in this large metropolitan city. However some patients from the surrounding districts may also be attending this hospital and will form part of the study.
- Study design:** Type of study: It was a follow up type of study with a minimum follow up of 2 months and maximum follow up of 18 months.
- Sample size with justification : 90**
Estimated sample size is around 90 at 7% allowable error.

d) Time frame to address the study:

The total study period was from October 2013 to April 2015.

d) Inclusion criteria

- Renal and ureteric calculus with size upto 2.5 cm.
- Patients who gave consent to be a part of the study.
- Those patients whose historical data is available and those who were followed for minimum 2 months after the procedure.

e) Exclusion criteria:

- Stones larger than 2.5cm**
- Lower third ureteric and bladder calculi.**
- Specific contraindications for ESWL such as obesity, hypertension and coagulopathies.**
- Patients who did not give consent for the study

f) Study pattern:

In all the patients fulfilling the study criteria, following parameters were noted using a detailed study proforma which is mentioned at the end. (Heading 1.6)

- PRE PROCEDURAL EVALUATION OF THE ESWL PATIENT
- Thorough history and physical examination
- Urological History included :
 - H/O pain – type, duration, location, radiation,
 - Pain associated with vomiting
 - Features of urinary tract infection e.g. fever, frequency of micturition
 - Haematuria present or absent
 - Similar complaints in the past
 - Past h/o urolithiasis / treatment for the same
 - Heaviness or swelling in the loin
- Medical history/ co morbidity eg. Hypertension, diabetes, bleeding disorder/patient on anti platelet agents/anticoagulants Patient has to stop taking drugs that can interfere with clotting at least 2 weeks beforehand for elective stone treatment.
- Examination included:
 - General survey
 - Local examination -- palpable swelling or lump in abdomen and examination of the external genitalia.

Investigations:

- Blood tests:
- Complete blood count,
- Coagulation profile : Prothrombin time, Partial Thromboplastin Time
- Serum creatinine
- Urine culture and sensitivity: sterilize urine; drain obstruction by prior DJ stenting when infection present
- Chest radiograph, ECG, lung function tests.

Imaging studies:

- Plain X ray KUB including KUB immediately before ESWL to confirm presence and location of stone
- Intravenous pyelogram including oblique views,
- Ultrasonography of entire abdomen including pelvis
- CT scan only if renal anomaly was suspected on ultrasonography/ IVP
- Isotope scan (in specific situations) to assess differential renal function in long-standing obstruction after appropriate drainage and recovery period
- Cystoscopy and retrograde pyelogram in specific situations when there is any suspicion of obstruction distal to the stone or if patient is allergic to contrast media, if stone diagnosis had not been established unequivocally, or if contrast needed for opacification of renal collecting system

TREATMENT

- All patients were subjected to Extra Corporeal shock wave Lithotripsy using a DORNIER COMPACT S ELECTROMAGNETIC Lithotripter.
 - Stone clearance was categorized under three categories:
 - Excellent: If only one session was required for total clearance
 - Good: If two sessions were required for total clearance
 - Average: If more than two sessions were required for total clearance.
- Each session was defined as one where 2000-2500 shocks would be used.

POST PROCEDURAL CARE AND FOLLOW-UP

- All patients were kept admitted for a minimum period of 24hrs.
- Continue IV antibiotics (if indicated)
- Oral fluid intake around 200 ml/hr
- Watch for immediate complications such as colicky pain or hematuria
- Discharge Instructions:
- Oral fluid intake 3-4 L/day
- Physical activity as tolerated
- Return to hospital for persistent colicky pain that is not responsive to oral pain medication,
- Temperature >38.5° C,
- Hematuria
- Discharge Medications :
- Antibiotic: orally for 5 days if instrumentation performed
- Pain relief: oral medication as required.
- Patients with DJ stent: Medications for bladder spasm usually given as follows: Pyridium, 100 mg 8hrly and Oxybutinin, 5-10 mg 8 hrly
- Outpatient follow up : At 2 weeks .

Examinations done:

- KUB to assess degree of stone disintegration and stone passage
- Ultrasound to exclude perirenal fluid collections and monitor hydronephrosis,
- urinalysis.
- Monitoring of blood pressure
- A stone free state was defined as no radiological evidence of stone or stone fragments following the procedure.
- If stone free: 3-month follow-up for KUB, ultra sound, urinalysis, blood pressure, metabolic evaluation
- If not stone free: additional sessions at 2 to 4 wk intervals, depending on amount of residual debris and presence of ureteral obstruction.
- Steinstrasse and hydronephrosis:
- Percutaneous drainage after 4 wk (maximum) if no progress
- Further checks at 2 wk intervals until stone free or auxiliary

procedure (PCNL or URS when ureteral debris does not clear within 8 wk)_.

The following variables had been broadly identified which were discussed to assess impact on ESWL

- Gender and Age of the patient
- Stone location in the kidney
- Stone size
- Number of stones
- Renal anomaly
- Whether stone was located in the ureter
- Stenting of the ureter done or not
- Co morbidity factors
- Stone density
- Skin to stone distance
- Type of Lithotripter

Outcome was assessed broadly under the following:

- Stone clearance: A stone free state was defined as no radiological evidence of stone or stone fragments following the procedure
- Complications

g) Statistical Analysis:

- Data collection:
- Data entry:

All patient data was entered as per the study proforma using Microsoft Excel which is mentioned under a separate heading below. This included all details of clinical, laboratory, radiology, treatment modality details , and follow up of the patient.

Data Tabulation:

The data was tabulated and summarized using frequency and percentage and graphs (bar diagram and pie chart).

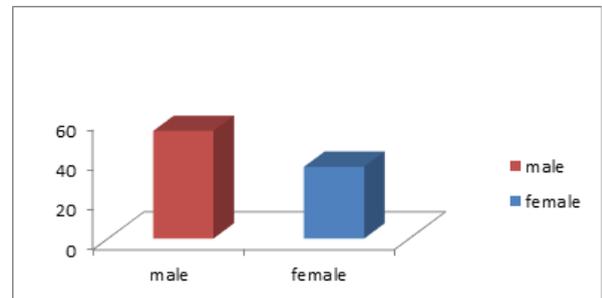
Data Analysis:

Data analysis was done using SPSS (Statistical Packages of Social Sciences, version 17.)

RESULTS AND ANALYSIS

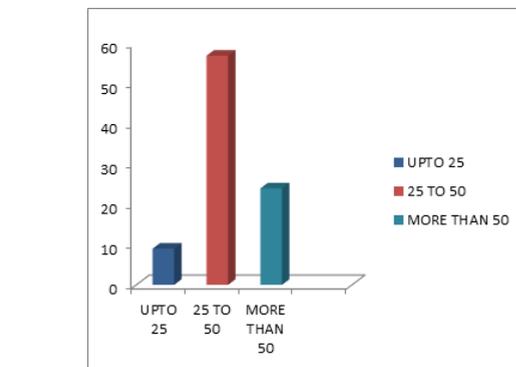
Results of our study are tabulated below. Each of the results is then discussed and analyzed in the context of similar studies reported in literature in the section on “discussion”

1. Gender distribution of our patients

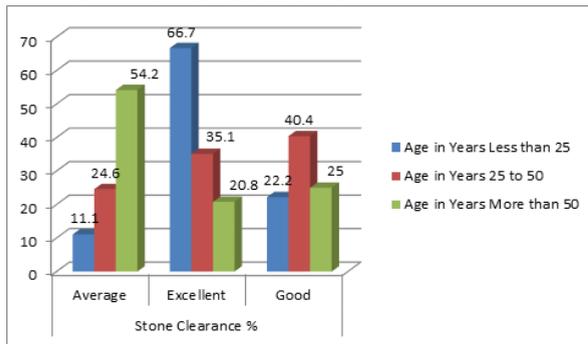


We had 54 males and 36 females in our study group.

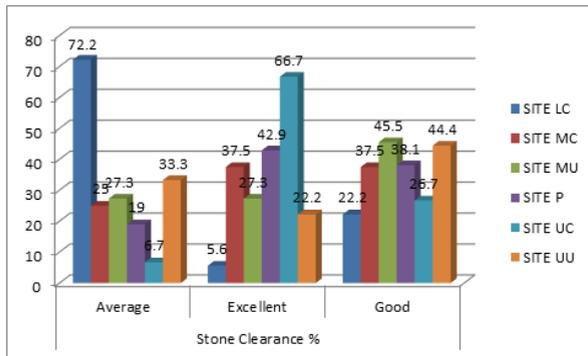
2. Age distribution of our patients.



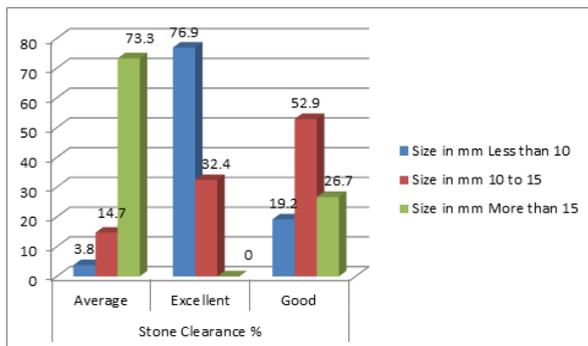
3. AGE Vs STONE CLEARANCE



4. LOCATION OF STONE vs STONE CLEARANCE



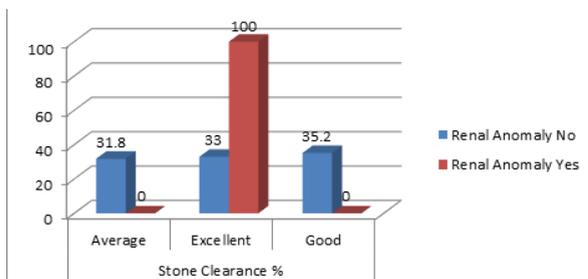
5. STONESIZE Vs CLEARANCE



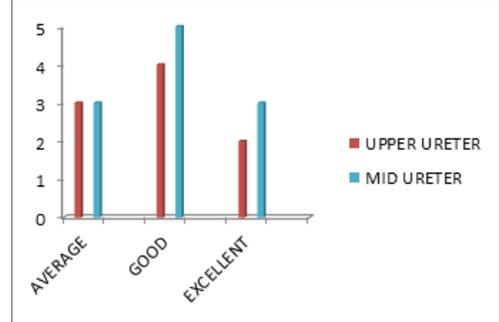
6. NO.OFSTONES Vs CLEARANCE



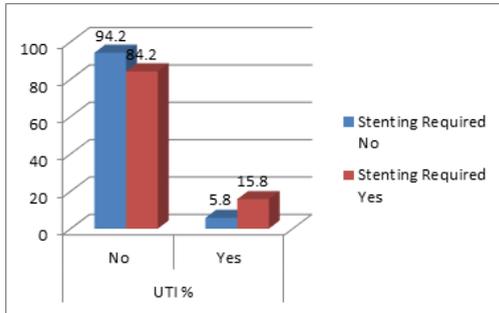
7. RENALANOMALY Vs STONE CLEARANCE



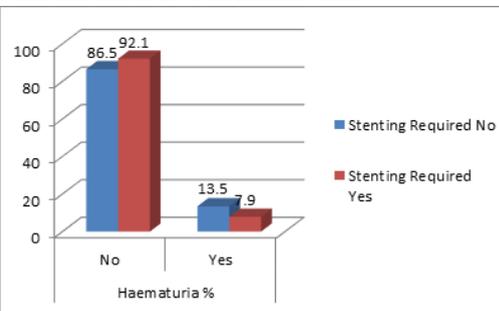
8 LOCATION OF CALCULI IN URETER ALONG WITH CLEARANCE



9. STENTING DONE Vs UTI

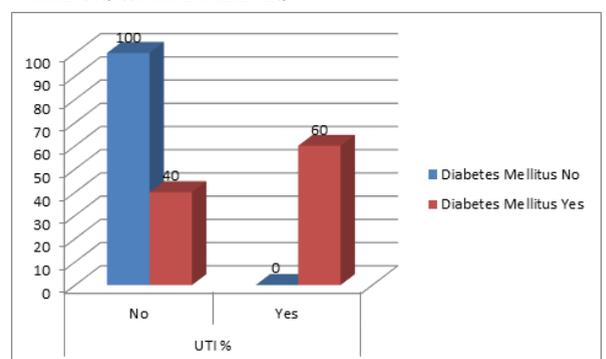


10. STENTING DONE Vs HAEMATURIA

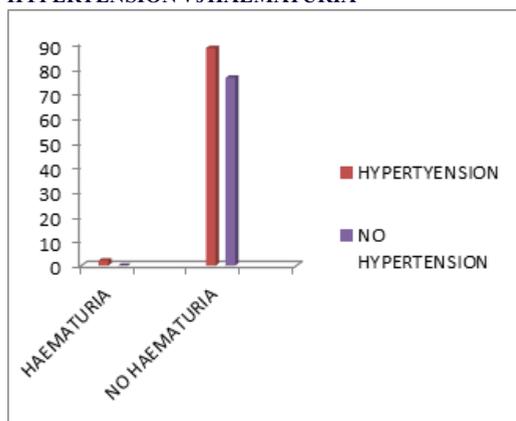


11. CO MORBIDITIES

1. URINARY TRACT INFECTION AS A COMPLICATION IN PATIENTS WITH DIABETES



11. HYPERTENSION Vs HAEMATURIA



DISCUSSION ON THE VARIABLES STUDIED WITH RESULTS ANALYSIS AND INCLUSION OF REVIEW OF LITERATURE

Our study was conducted on ninety patients undergoing ESWL in a tertiary level teaching hospital and aimed at determining the impact variables (mentioned previously) on the outcome..

- Age of the patient is an important variable predicting the outcome of ESWL. It is well known that as the age increases, the overall function as also the ability of the kidney to expel the stone decreases²¹ due to decrease in urinary flow. It was seen that 6 out of 9 patients in the age group up to 25 years i.e. 66.66%, had excellent stone clearance, 2 patients (22.22%) had good stone clearance and 1 patient (11.11%) had average stone clearance. Of the 56 patients in the age between 25 to 50 years .23 patients (56%) had good stone clearance ,21 patients (37.5%) had excellent stone clearance and 12 patients (21.42%) had average stone clearance. 25 patients were of age group between 50 -75 years .7 of these i.e 28% had good stone clearance , 5(20%) had excellent stone clearance while 13 patients (52%) had average stone clearance. It appeared from our study that as the age increases, stone clearance is not as effective. Our finding therefore matches with the study of Ng CF² that is mentioned in literature ESWL however is considered a good treatment modality in the paediatric age group with several studies reporting this^{24,25,26}. In our study there were no patients in the paediatric age group and hence we could not comment on this aspect.
- The location of the calculus in the kidney has a significant impact on the success rate of ESWL .Stone clearance is better in upper and middle calyx compared with that in lower calyx. In our study 21 patients had calculi in the renal pelvis . While 9 patients i.e. 42.85% had excellent stone clearance, 8 (38.09%) had good clearance and 4 (19.04%) had average clearance. In the 15 patients who had calculi in the upper calyx, 60% (9 patients) had excellent stone clearance , 26.66% (4 patients) had good stone clearance and 2 patients i.e.13% approximately had average stone clearance. Out of the 16 patients with calculi in middle calyx , 6 patients each (37.5%) had each excellent / good stone clearance while 4 (25%) had average stone clearance. 18 patients had calculi in lower calyx . Here the pattern of stone clearance was quite opposite to that seen for upper and middle calyceal calculi. Only 1 patient (5.55%) had excellent stone clearance, 72.22% had average stone clearance. 4 patients i.e 22.22% had good stone clearance But based on what we found in our study we can conclude that the stone clearance is definitely affected by the position of the stone in the kidney .The clearance is less in lower calyx compared to that in middle and ,upper calyx , as well as upper ureter and mid ureter. In a large study done by Obek C et al³, 687 patients with isolated caliceal stones were treated with ESWL. The overall stone free rate was 66%, 73% and 71% for lower ,middle and upper caliceal stones respectively and he concluded that ESWL efficacy is *not* significantly different in upper, middle or lower pole
- The Number of stones, (indicating stone burden), is an important factor which predicts the outcome of ESWL . Lesser the number of stones better is the stone clearance In our study 67 patients had single calculus. 26 of these (i.e 38.08 %) had excellent stone clearance, an equal number had good stone clearance and 15 of them (i.e. 22.38%) had average stone clearance. 23 of our patients

had 2 renal calculi. While 5 of these (21.73%) had excellent stone clearance, another 5 had good stone clearance and 13 patients (56.52 %) had average stone clearance .Our study revealed that as the number of stones increase, and thereby the stone burden, it takes more sessions to achieve a stone free state as compared to a situation where there were lesser number of stones. This is corroborated by Lingeman JE et al¹ in their study on “The role of Lithotripsy and its side effects” where they say that the morbidity of ESWL increases with increasing stone burden as compared against other methods of stone removal.

- Renal Anomalies: There are certain anatomic factors, either congenital or acquired, that can hinder stone clearance after ESWL Any patient with obstruction distal to the targeted stone should not undergo ESWL treatment. Study reported by Trapeznikova et al⁵ where ESWL was carried for 139 patients (197 sessions) for a variety of renal anomalies where they reported an average of around 1.8 ± 0.2 sessions per patient with the highest of 3.8± 0.8 sessions for patients with a horseshoe kidney, and the lowest of 1.3± 0.45 sessions for patients with lumbar dystopy of the kidney. They concluded that low invasive approaches were suited for patient with urinary tract anomalies. Out of our 90 patients , only 2 patients (2.22%) presented with renal anomalies. A 38 year old female patient had horseshoe kidney. She had a 12mm calculus in left calyx in left kidney and she underwent a single session of ESWL with 2000 shock waves The patient did not require stenting and stone clearance was excellent . The patient was followed up to 3 months and so far no recurrence has been noted . Another patient ,a 27 year male patient with bilateral polycystic kidneys had a 15mm calculus in upper calyx of the right kidney .He underwent a single ESWL session with 2500 shock waves ,and DJ stenting. Stone clearance was excellent.
- Ureteric calculi: ESWL is considered suitable for stones less than 1cm in proximal ureter⁶.For larger stones , more than 1cm in size, flexible ureteroscopic lithotripsy is the primary approach²³. PCNL is reserved for those with impacted calculi that are refractory to other treatment ,those with dilated collecting system ,large stone burden and those with distal ureteric strictures⁷. In a study Yen cui et al⁸ , where ESWL was compared against Holmium laser lithotripsy for management of Ureteral stones ,ESWL was found to be the first line therapy for proximal ureteric stones of size 8 to 15mm while holmium laser lithotripsy was the costlier option. 11 of our patients had calculi in mid ureter.3 patients i.e. 27.27% had average stone clearance, other three i.e. 27.27% had excellent stone clearance and 5 patients i.e. 45.45% had excellent stone clearance . 9 patients had calculi in upper ureter .Out of 9, 3 patients i.e 33.33% had average stone clearance, 4 patients i.e 44.44% had good stone clearance and 2 patients i.e 22.22% had excellent stone clearance. Patients who had mild to moderate or severe hydronephrosis required stenting and stone clearance was reasonably good with no recurrence so far in follow up. Literature search has shown a study done by Joshi HN⁹ on 216 patients which says that ESWL is the first line preferred choice for upper ureteric stones of size less than 1cm.. We did not use ESWL for any distal ureteric calculus and preferred to perform ureteroscopic removal for them.
- Stenting of the ureter: In patients with bigger stones , in those whose fragmentation is not good and those with moderate to severe hydronephrosis DJ stenting is required. It enhances clearance of the fragments and free flow of urine post ESWL. Pettenati et al¹⁰ and Mustafa M et al¹¹ were of the opinion that stenting may not enhance stone clearance and may cause complications such as pain ,urgency and haematuria. In our study we decided to perform prophylactic stenting in all patients with stone size above 1.5 cm irrespective of other criteria. 38 patients underwent DJ stenting under antibiotic coverage while the other 52 were not stented. Out of the 38 who were stented, 28 patients i.e. 73.68% had complete stone clearance while in the other 10 stented patients i.e. 26.31 % the stones did not clear completely initially. These patients were advised to follow up regularly and subsequently required more sessions for complete stone clearance. Therefore in our study it was seen that a majority of the stented patients cleared stones completely and in this subgroup of stented patients, this intervention i.e. stenting, appeared to be beneficial. Out of 38 stented patients , while 6 patients i.e. 15.78% developed urinary tract infection.. Thus we see that there is a difference in opinion regarding the usefulness or otherwise of prior stenting in patients undergoing ESWL.

• Co Morbidity:

1. Diabetes and urinary tract infection : The majority of complications occurring after ESWL are minor, the more severe ones being gross haematuria, pain and perinephric haematoma²⁸. Bacteriuria may also occur in some cases which can lead to sepsis and even abscess formation rarely. Out of 90 patients ,15 patients i.e. 16.66% had diabetes mellitus.9 patients i.e. 60% of the patients developed urinary tract infections while no UTI was seen in the rest of the patients. Out of those 9 patients , 3 patients i.e. 33.33% were stented and 6 patients i.e. 66.66% did not have stent in situ. Patients with diabetes mellitus have increased risk of developing urinary tract infections compared to those without diabetes mellitus . Though all our patients with diabetes had their sugars under control ,it is proved that a better sugar control was desirable in these patients to avoid infections.
2. Uncontrolled hypertension and hematuria: Uncontrolled hypertension is a contra-indication for ESWL since there is possibility of haematuria and even a chance of a haematoma formation resulting in infections of the upper urinary tract , obstruction to urine flow and then hydronephrosis³⁰. Thus control of hypertension is essential to prevent haematuria. In a study by Andreas Skolarikos et al¹² hypertension was seen as a potential risk factor for haematuria and haematoma formation following ESWL. Massive retroperitoneal haemorrhage leading to death has also been reported. In our study out of 90 patients, 14 patients were hypertensive. Out of these 14 , 2 patients i.e. 14.28 % developed haematuria following ESWL. Among these 2 patients , 1 patient had been stented and the other was not. The patients with hypertension have increase risk of haematuria compared to those without hypertension .
- Stone composition and density also affects the stone clearance .Cystine calculi respond very poorly to ESWL¹³. Intracorporeal lithotripsy can be used for such stones. Also the brushite stones are most resistant to ESWL followed by calcium oxalate monohydrate, struvite, calcium oxalate dehydrate and then uric acid in descending order⁶⁵. In a study done by Hamdoun Abdelaziz et al¹⁴ 89 patients received ESWL for renal and upper ureteric calculi . They concluded that calculi with stone density less than 500 HU were likely to have higher success rate by ESWL.
- Skin to stone distance is an important factor which predicts the outcome of ESWL. A study done by Pareek et al¹⁵ says that the SSD may predict the outcome after ESWL of lower pole kidney stones. ESWL in patients with an SSD greater than 10 cm is likely to

CONCLUSIONS

- ESWL is an excellent, safe, non invasive modality with minimal morbidity, hospital stay and complications for the treatment of a certain subset of patients with urinary calculi in the kidney and to the level of the mid ureter up to 2.5cm in size. However its application to lower ureteric calculi is controversial with ureteroscopy removal being the standard of care in this subset of patients²⁰.
- Increasing age but not the gender of the patient decreases the efficacy in terms of stone clearance²².
- Increased stone burden in terms of the size of the stone (or the combined size of more than one stone) affects clearance by increasing the number of sessions required for a complete stone free state. On this point too our findings more or less matched with available literature though one study did mention that size of stone up to 30mm does not affect clearance¹⁶. But this is more likely to be an exception.
- Pelvic, upper and middle calyceal calculi had better clearance as compared to those in the lower calyx and a chance of false recurrence is always there unless extreme care is taken to ensure complete clearance with multiple sessions or another treatment modality such as PCNL¹⁹ is added on. On this point there has been difference of opinion between conclusions of our study and others with some reviewed studies finding ESWL suitable even for staghorn calculi.¹⁷ Again this appears to be an exception rather than the rule.
- ESWL is a good modality for stones in upper ureter of size up to 1cm. Stenting is a good option in stones from 1.5 cm onwards based on presence of hydronephrosis and degree of obstruction²³. For middle ureteric stones it can still be used as a treatment modality. But for lower uretic calculi ureteroscopy is definitely the preferred modality as against ESWL.
- Stenting enhances the passage of fragments in renal and ureteric calculi and in today's age of advanced care available against

infection, prophylactic stenting especially in stones of 1.5 cm or more is beneficial rather than harmful.

- ESWL should be used in patients whose diabetes and hypertension is controlled to avoid complications.

Finally, in conclusion, ESWL is today established beyond doubt in terms of its efficacy and superiority as a treatment modality over a large segment of patients with urinary calculi. There are several variables affecting the outcome of ESWL and this is the most important thing to be kept in mind in trying to achieve a complete stone free state in a patient.

Recommendations

Based on the conclusions of our study we can give the following recommendations:

1. ESWL can be recommended as the treatment of choice in patients with urinary calculi up to 2.5 cm in size provided they are in the kidney and up to the mid ureter.
2. It is not to be recommended routinely for lower ureteric calculi since better methods (eg. Ureteroscopy removal) are available for these patients.
3. It is recommended for patients of any gender, though we have to be more careful with older patients where stone clearance may be poorer due to overall decrease of kidney function. However, it is also recommended that patients with larger or more number of calculi be counselled prior to the procedure itself that more number of sessions may be required for clearance due to increased stone burden.
4. Stenting of the ureter is recommended in patients with stones more than 1.5cm in size since it enhances clearance of the fragments.
5. ESWL is better avoided in a patient with a renal anomaly and in those with uncontrolled diabetes and hypertension.

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